

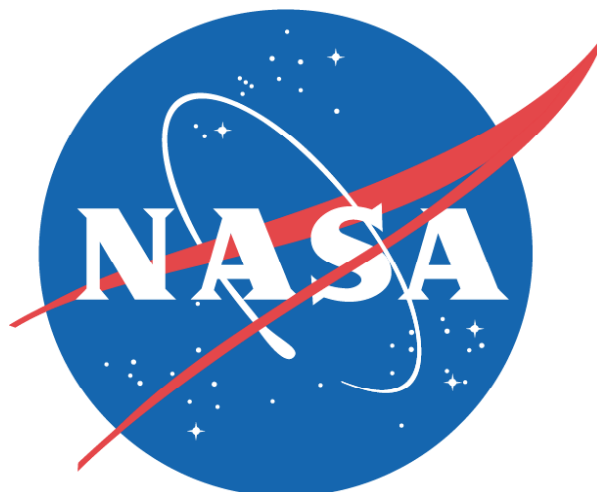
**Office Work Instruction**

HQOWI 1800-AM001 REV. F  
July 6, 2001

Responsible Office: AM/Office of the Chief Health & Medical Officer

**Subject: Agency Medical Policy and Guidance Formulation**  
**(Human Space and Atmospheric Flight and Supporting Activities)**

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**OFFICE WORK INSTRUCTION**

**AGENCY MEDICAL POLICY and**  
**GUIDANCE FORMULATION**  
**(Human Space and Atmospheric Flight and Supporting**  
**Activities)**

Original Approved and Signed by:

Dr. Richard S. Williams MD, FACS  
Chief Health and Medical Officer

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### DOCUMENT HISTORY LOG

Status (Baseline/ Revision/ Canceled)	Document Revision	Effective Date	Description
Baseline		02/01/99	
Revision	A	04/30/99	Incorporates changes made in response to comments from the Code U review and the DNV Pre-Assessment Report.
Revision	B	08/17/99	Incorporates changes to eliminate letter version designations and correct titles on reference documents.
Revision	C	11/01/99	Administrative change to reflect the fact that the Medical Policy Document is no longer in draft but is signed and official, and that it is a reference document, not a quality record, remove reference to Occupational Health NPC 1800, reflect the use of NMI 8900 since the draft NPD 8900 is not complete, and make the person responsible for the process the Director, Office of Health Affairs since there is currently no PD for the position of Program Executive in Aerospace Medicine and Psychology.
Revision	D	02/29/00	Removes draft status for NMI 8900, Astronaut Medical and Dental Observation Study and Care Program to NPD 8900, Astronaut Medical and Dental Observation Study and Care Program
Revision	E	05/01/00	Administrative change to transfer Responsible Office from Code U to Code AM. Former Code U # was U012.
Admin Update	E	05/04/01	Administrative changes to achieve agreement in section 5, 6 and 7 in the language for quality record identification. Addition of outside process link to the approval process of NPD, NPG, and NPC documents in step 4 of section 5 and 6.
Revision	F	07/06/01	Administrative changes to reflect new titles and additional oversight responsibilities for the Office of the Chief Health and Medical Officer (OCHMO)

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### 1. Purpose

This Office Work Instruction (OWI) defines the process for the formulation and approval of medical policy and Guidance for NASA's human space flight program.

### 2. Scope and Applicability

This OWI applies to the activities of the Office of the Chief Health and Medical Officer staff in formulating NASA medical policies and guidance that are under the purview of the NASA Medical Policy Board (MPB). The objective of these policies is to ensure: 1) protection of NASA space flight and atmospheric flight crew members and individuals engaging in supporting activities to the greatest extent possible, 2) Agency-wide consistency in addressing hazards associated with space and atmospheric flight and supporting activities, 3) Agency-wide consistency in medical standards for space and atmospheric flight crew members. Within the Office of the Administrator, the Office of the Chief Health and Medical Officer (OCHMO) has lead responsibility for NASA medical policy and guidance for human space and atmospheric flight and supporting activities.

### 3. Definitions

- 3.1 Chief Health and Medical Officer (CHMO) –Serves as the principal advisor to the Administrator and other senior NASA officials on health and medical issues, budget and policy and provides oversight of health care delivery, professional competency, quality assurance, and the safety of human and animal research subjects.
- 3.2 Medical Policy Board (MPB) - A board consisting of physician representatives from NASA and other federal agencies which recommends NASA medical policy and guidance for human space and atmospheric flight. A full description of the MPB is provided in NASA Policy Charter 1000.3. The NASA Organization Section 6.19 NASA Medical Policy Board and Aerospace Medicine Board describes NASA Medical Boards in Support of Space Flight Operations. The CHMO is the Chairperson of the Medical Policy Board (MPB).

### 4. Reference Documents

- 4.1 NPG 1000.3, The NASA Organization
- 4.2 NPD 8900.1, Responsibilities in Support of Human Space Flight
- 4.3 NPD 7100.8, Protection of Human Research Subjects
- 4.4 NPD 8900.3, Astronaut Medical and Dental Observation Study and Care Program

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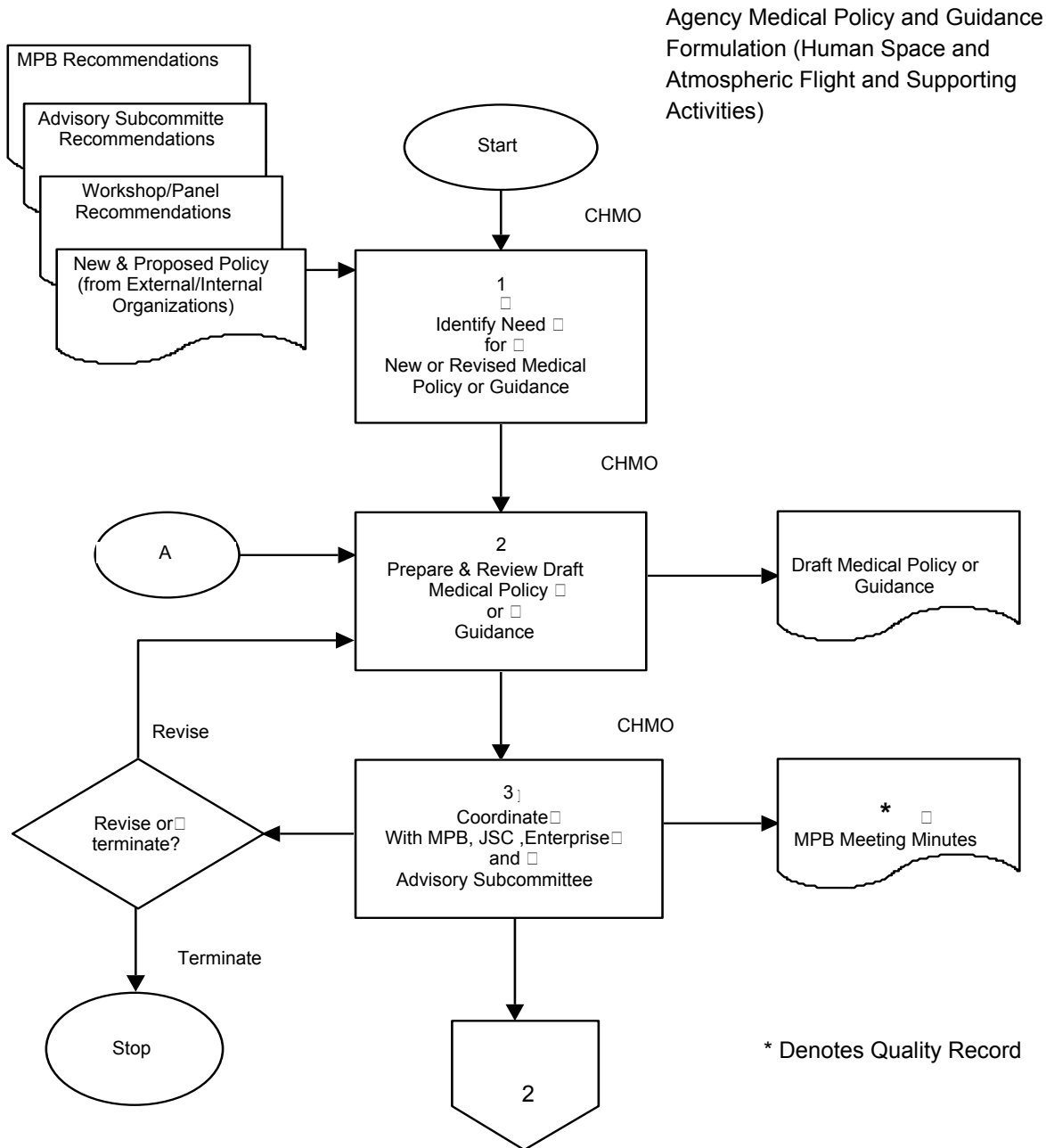
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### 5. Flowchart



KEY: □

CHMO: Chief Health and Medical Officer □

□

MPB: Medical Policy Board □

NPD: NASA Policy Document □

NPG: NASA Policy Guidance □

NPC: NASA Policy Charter □

AA: Associate Administrator □

□

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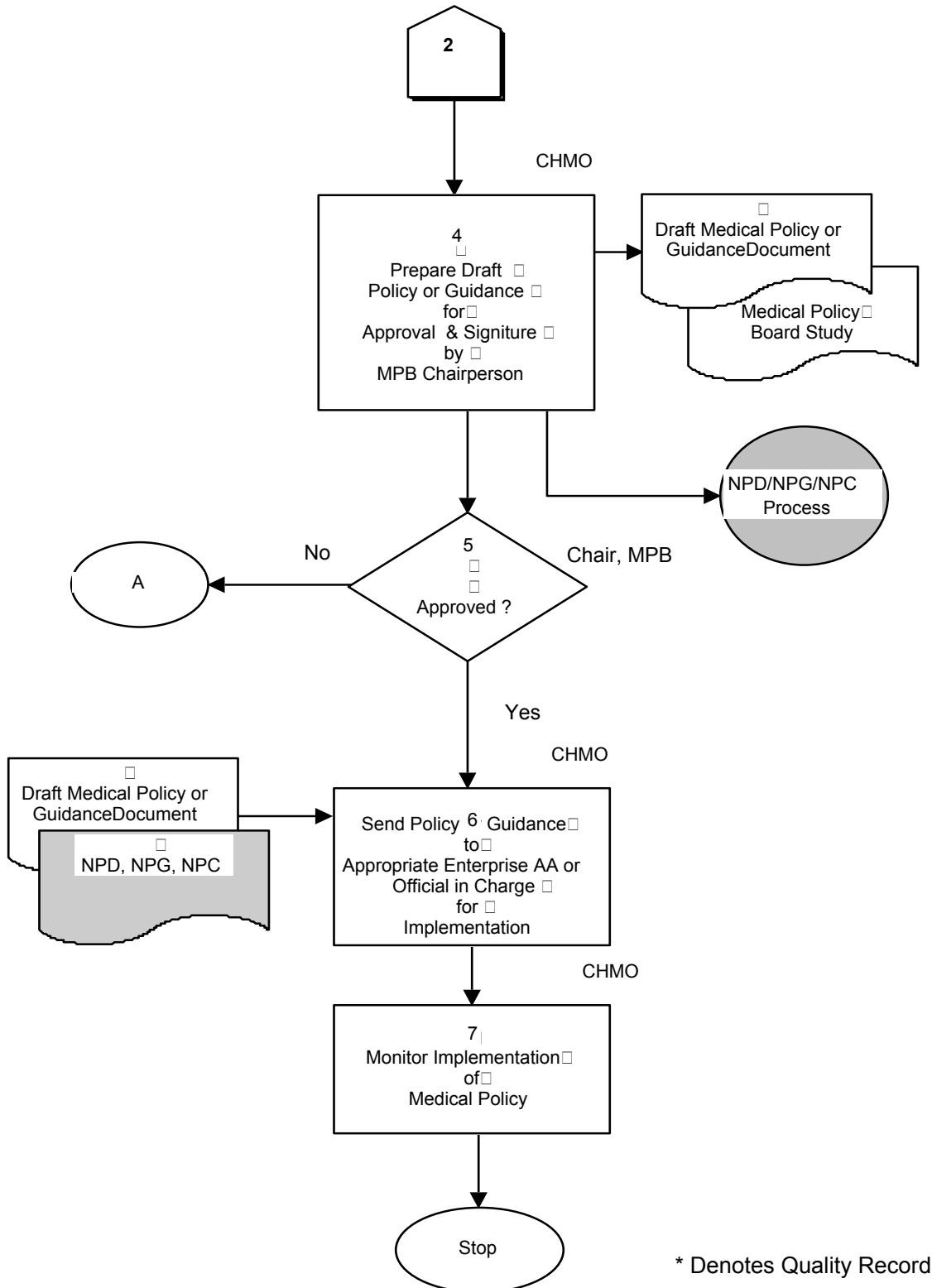
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\* Denotes Quality Record

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### 6. Procedure

The number at the left of the process activity table refers to the flowchart step in Sec. 5.

#	Responsible Party	Activity Description
1	Chief Health and Medical Officer	<p>Identify the need for new or revised medical policy or guidance. The stimuli for new or revised policy or guidance may come from within NASA or from other organizations. A stimulus for action could include issues identified by the MPB, subcommittees of the NASA Advisory Committee, or expert workshops or panels, as well as new requirements due to of new laws or regulations. Recommendations may also come from the NASA Enterprises, functional staff offices or other NASA staff. The results of MPB studies are also an input.</p> <p>Present recommended actions for approval to the Chair, MPB. Recommendations could include revisions to existing MPD policies or formulation of new policies or guidance. It could also be a recommendation to form an MPB working group to conduct a study. The new medical policy or guidance will be documented in the minutes of the Medical Policy Board and will be transmitted to the appropriate official-in-charge by memorandum. If it is determined that no action is required, then there may be an output in the MPB minutes or an electronic mail message to MPB members indicating the outcome.</p>
2	Chief Health and Medical Officer	<p>If it is determined that new or revised policy or guidance is required, a draft is prepared and reviewed with the MPB Chair.</p> <p>Comments are incorporated and the draft policy/guidance is prepared for coordination outside of the Office of the Chief Health and Medical Officer. It is submitted to the MPB Executive Secretary who adds the topic to the agenda for review and approval at the next meeting of the MPB.</p>

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- |   |                                  |   |
|---|----------------------------------|---|
| 3 | Chief Health and Medical Officer | <p>Coordinate draft policy /guidance with MPB members, non-Office of the Chief Health and Medical Officer staff involved in medical policy for human space flight and, as appropriate, with Advisory Subcommittee to obtain comments and approval. As needed, hold meeting(s) of the MPB to review and approve the final policy/guidance. If a MPB meeting is held, comments and decisions are reflected in <u>the MPB Meeting Minutes</u> which are distributed to the MPB members. Return to Step 2 to revise policy to incorporate comments received during coordination. Repeat coordination, as required. If it is concluded that no new or revised policy is needed, terminate action.</p> <p>If a study is to be performed, form ad hoc MPB working group. The working group produces the study and presents the results to the MPB.</p> |
| 4 | Chief Health and Medical Officer | <p>Prepare draft medical policy /guidance documents after coordination is completed. Present policy to the Chair, MPB for final approval and signature. If not approved, revise as required to obtain approval.</p> <p>Present studies for approval. Approved policy documentation requiring further processing to revise or create a new NPD, NPG or NPC are forwarded to the outside process governing approval of Agency policy procedures. If not approved, revise as required to obtain approval.</p>  |
| 5 | Chair, MPB                       | <p>Review, approve and sign policy, guidance or study. If it is not approved go to step 2.</p>  |
| 6 | Chief Health and Medical Officer | <p>Arrange for distribution of policy or guidance to appropriate AA or Official-in-charge.</p>  |
| 7 | Chief Health and Medical Officer | <p>Monitor implementation of medical policy. As appropriate, report to the MPB on the status of policy implementation.</p>  |

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<i>Record Identification</i>	<i>Owner</i>	<i>Location</i>	<i>Media Electronic/ Hard Copy</i>	<i>Schedule and Item Nos.*</i>	<i>Retention/ Disposition</i>
Medical Policy Board Meeting Minutes	Chief Health and Medical Officer	Code AM	Hard Copy	Schedule 1, Item 14B.1	Permanent Retire to FRC when 2 years old. Transfer to NARA when 20 years old, whichever is sooner.

\* Quality Records are retained in accordance with the referenced schedule and item number from NPG 1441.1, *NASA Records Retention Schedules*